



UNITED STATES DEPARTMENT OF COMMERCE
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| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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07/953,680 09/29/92 SHEPHERD

25M1/1001

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A UTSK: 142
EXAMINER

HANTIS, K

ART UNIT PAPER NUMBER

2505
DATE MAILED:

10/01/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☐ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice of Art Cited by Applicant, PTO-1449. ✓
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☒ Notice re Patent Drawing, PTO-948. ✓
- ☒ Notice of Informal Patent Application, Form PTO-152. ✓
- ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 1-33 are pending in this application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-33 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Art Unit 2505

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 20 -24 and 26-27 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Anderson et al.

Anderson specifically states in the abstract that the present study was made with an integrating sphere spectrometer (see Figure 1) and application of Twersky's theory for the multiple scattering of waves permitted separation of the effects of absorption and scattering and the light transmittance on nonhaemoglobin blood i.e. unaltered whole blood. It is shown that the relationship between light scattering and red-cell concentration is parabolic and that the absorption of light within the erythrocyte is the same as in a haemoglobin solution, i.e. altered whole blood. See pages 174-183 in regard to the molar extinction coefficients, and the plurality of substantially monochromatic wavelengths. Note that Anderson inherently has correction for calculated concentrations, since the results of Anderson would have no meaning without such a correction. (See page 180, last line of the first paragraph).

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office

action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 2-9, 1P-19, 25 and 28-33 are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson.

Anderson in an unaltered whole blood measurement system fails to disclose the specific depth of the sample, the specific detecting area, the specific distance from the sample, the specific half aperture angle of radiation emanating from the sample, computing an error index, selecting a wavelength range for bilirubin or sulfhemoglobin, red blood cell scattering vector and non specific scattering vector.

At the time invention was made, it would have been obvious to one with ordinary skill in the art to modify Anderson to incorporate the specifics cited above. The rationale for this modification would have arisen, since it is apparent that the depth of the sample, the detecting area, the distance from the

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Art Unit 2505

sample, the half aperture angle all have a specific effect on the overall measurement and it^{is} a matter of design engineering to select which depth, area distance, angle is required for a particular outcome. Anderson specifically shows that for different depths, different wavelengths etc., different results occur. Thus, a specific relationship between all of the specifics cited above are well known and it is up to the person conducting the measurement, what specifics are required for that specific outcome to occur. As for the error index, bilirubin, sulfhemoglobin, red blood cell scattering and non specific scattering vectors, the same reasoning cited above applies. It is up to the person conducting the measurement, as to what specifics are required for that specific outcome to occur.

In regard to claims 12-15, see page 177, second to last line of the first paragraph.

Any inquiry concerning this communication should be directed to K. Hantis at telephone number (703) 308-4801.

KH

Hantis/gd
September 22, 1993

Doris L. Wilko
SUPERVISOR
ER



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER

FILING DATE

FIRST NAMED APPLICANT

ATTY DOCKET NO./TITLE

953,680

DATE MAILED:

NOTICE OF INFORMAL APPLICATION

(Attachment to Office Action)

This application does not conform with the rules governing applications for the reason(s) checked below. The period within which to correct these requirements and avoid abandonment is set in the accompanying Office action.

A. A new oath or declaration, identifying this application by the application number and filing date is required. The oath or declaration does not comply with 37 CFR 1.63 in that it:

1. ☒ does not identify the city and state or foreign country of residence of each inventor, A. P. Sheppard
2. ☐ does not identify the citizenship of each inventor.
3. ☐ does not state whether the inventor is a sole or joint inventor.
4. ☐ does not state that the person making the oath or declaration:
 - a. ☐ has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.
 - b. ☐ believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.
 - c. ☐ acknowledges the duty to disclose information which is material to the examination of the application in accordance with 37 CFR 1.56(a).
5. ☐ does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application serial number, country, day, month, and year of its filing.
6. ☐ does not state that the person making the oath or declaration acknowledges the duty to disclose material information as defined in 37 CFR 1.56(a) which occurred between the filing date of the prior application and filing date of the continuation-in-part application which discloses and claims subject matter in addition to that disclosed in the prior application (37 CFR 1.63(d)).
7. ☐ does not include the date of execution.
8. ☐ does not use permanent ink, or its equivalent in quality, as required under 37 CFR 1.52(a).
9. ☐ contains non-initialed alterations (See 37 CFR 1.52(e)).

10. ☒ Other: no post office address for John M. Steinke

B. Applicant is required to provide:

1. ☐ A statement signed by applicant giving his or her complete name. A full name must include at least one given name without abbreviation as required by 37 CFR 1.41(a).
2. ☐ Proof of authority of the legal representative under 37 CFR 1.44.
3. ☒ An abstract in compliance with 37 CFR 1.72(b). (Too Long)
4. ☒ A statement signed by applicant giving his or her complete post office address (37 CFR 1.33(a)) for John M. Steinke
5. ☐ A copy of the specification written, typed, or printed in permanent ink, or its equivalent in quality as required by 37 CFR 1.52(a).
6. ☐ Other: